Serial No. 09/715,902
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a2

5. (Amended) The method of claim 1, wherein the dendritic cells originate from a human subject.

6. (Amended) The method of claim 1, wherein the cationic detergent is cetyl trimethyl ammonium bromide.

7. (Amended) The method of claim 1, wherein the cationic detergent is cetrimide.

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14. (Amended) The method of claim 1, wherein the dendritic cells are cultured for about 5 to about 10 days prior to transfection.

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16. (Amended) The method of claim 1, wherein said polynucleotide is provided in the form of a plasmid.

17. (Amended) The method of claim 1, wherein said polynucleotide encodes an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor.

18. (Amended) The method of claim 17, wherein the antigen is associated with human immunodeficiency virus, herpes simplex virus, hepatitis B virus, hepatitis C virus, human papillomavirus, influenza A virus, meningitis A, meningitis B, or meningitis C.

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30. (Amended) The method according to claim 1, wherein said microparticles have diameters ranging from about 500 nm to about 30 μm.

Please add claims 32-53 as follows:

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32. (Newly added) The method of claim 17, wherein the detergent is cetyl trimethyl ammonium bromide.

33. (Newly added) The method of claim 17, wherein said polynucleotide encodes a viral antigen.

34. (Newly added) The method of claim 17, wherein said polynucleotide encodes a tumor antigen.

35. (Newly added) The method of claim 17, wherein said polynucleotide encodes a bacterial antigen.

36. (Newly added) The method of claim 17, wherein said polynucleotide encodes a parasitic antigen.

37. (Newly added) The method of claim 17, wherein said polynucleotide encodes a fungal antigen.

38. (Newly added) The method of claim 19, wherein said polynucleotide encodes a viral antigen.

39. (Newly added) The method of claim 19, wherein said polynucleotide encodes a tumor antigen.

40. (Newly added) The method of claim 19, wherein said polynucleotide encodes a bacterial antigen.

41. (Newly added) The method of claim 19, wherein said polynucleotide encodes a parasitic antigen.

42. (Newly added) The method of claim 19, wherein said polynucleotide encodes a fungal antigen.

43. (Newly added) The method of claim 19, wherein said polynucleotide encodes a human immunodeficiency virus antigen, a herpes simplex virus antigen, a hepatitis B virus antigen, a hepatitis C virus antigen, a human papillomavirus antigen, an influenza A virus antigen, a meningitis A antigen, a meningitis B antigen, or a meningitis C antigen.

44. (Newly added) The method of claim 19, wherein the detergent is cetyl trimethyl ammonium bromide.

45. (Newly added) The method of any of claims 1-23 and 29-44, wherein at least a portion of said polynucleotide is adsorbed on the surface of said microparticles.

46. (Newly added) The method of claim 1, wherein at least a portion of said polynucleotide is entrapped within said microparticles.

47. (Newly added) The method of claim 1, wherein at least a portion of said polynucleotide is both adsorbed on the surface of said microparticles and entrapped within said microparticles.

48. (Newly added) The method of claim 17, wherein at least a portion of said polynucleotide is entrapped within said microparticles.

49. (Newly added) The method of claim 17, wherein at least a portion of said polynucleotide is both adsorbed on the surface of said microparticles and entrapped within said microparticles.

50. (Newly added) The method of claim 19, wherein at least a portion of said polynucleotide is entrapped within said microparticles.

51. (Newly added) The method of claim 19, wherein at least a portion of said polynucleotide is both adsorbed on the surface of said microparticles and entrapped within said microparticles.

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52. (Newly added) The method of any of claims 1-7, 13-23, 29-44 and 46-51, wherein the polymer is a poly(lactide-co-glycolide).

53. (Newly added) The method of any of claims 1-15, 19-23, 29-32, 44 and 46-51 wherein the polynucleotide is an expression vector encoding an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor.

STATUS OF CLAIMS

Claims 1-53 are presently pending. Claims 32-53 have been added.

By the above amendment, claims 1, 5-7, 14, 16-18 and 30 are amended. A separate sheet entitled "**Version with Markings to Show Changes Made**" is provided to illustrate the amendments to the claims. All claims are illustrated for the Examiner's convenience.

Support for *ex vivo* transfection in claim 1 is found throughout the specification, for example, at p. 19, lines 22-23.

Support for an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor can be found, for example, at p. 11, lines 10-12 of the specification.

Support for culturing dendritic cells for about 5 to about 10 days prior to transfection can be found, for example, at p. 6, line 30 of the specification.

Support for microparticles having a diameter ranging from about 500 nm to about 10 μm can be found, for example, at p. 9, line 24 of the specification.

Support for polynucleotide that is adsorbed on and/or entrapped within microparticles can be found, for example, at p. 21, lines 1-2 of the specification.

Support for antigens associated with herpes simplex virus, hepatitis B virus, hepatitis C virus, human papillomavirus and influenza A virus can be found, for example, at p. 16, line 21 to p. 18, line 17 of the specification.

Support for poly(lactide-co-glycolide) can be found throughout the specification (see, e.g., p. 3, line 23).

Support for the case where the polynucleotide is an expression vector encoding an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor can be found, for example, at p. 20, lines 5-8 and at p. 11, lines 10-12 of the specification.

REMARKS

Claims 1-23 and 29-31 are rejected under 35 U.S.C. 103(a) as obvious over Song et al. in view of Hedley et al. and Fattal et al.

In brief, the Office Action notes that Song et al. differs from the present invention by not teaching the claimed combination of polynucleotide, biodegradable polymer and cationic detergent as a transfection agent for dendritic cells. The Office Action contends, however, that Hedley et al. supplements Song et al. by teaching the use of microparticles containing biodegradable polymer and plasmid DNA to introduce and express antigens encoded by the plasmid DNA in antigen presenting cells such as dendritic cells. The Office Action further recognizes that Hedley et al. does not teach the use of microparticles that contain cationic detergent, but asserts that Fattal et al. provides motivation for including a cationic detergent such as CTAB in the preparation of transfection agents comprising biodegradable polymers and polynucleotides.

The Applicants traverse this rejection and its supporting remarks.

In order to establish a *prima facie* case of obviousness under 35 U.S.C. 103, (a) there must be some suggestion or motivation to modify/combine the references of record, and (b) there must be a reasonable expectation of success. See MPEP §2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *Id.* The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination